

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Confirmation No. 3314
Gerald Cagle et al. : Group Art Unit: 1618
Application No. 10/715,055 : Examiner: Fay, Zohreh A.
Filed: November 17, 2003 : Atty Dkt No.: 007109.00001
For: METHOD OF TREATING :
OPHTHALMIC INFECTIONS WITH :
MOXIFLOXACIN COMPOSITIONS :

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to the duty of disclosure under 37 CFR §§ 1.56 and 1.97-1.98, the documents listed on the three attached PTO forms PTO/SB/08a are being brought to the attention of the Examiner. The Examiner is requested to initial the space adjacent each document's entry on the forms and to return a copy of the initialed forms to confirm that the documents have been considered and have been officially made of record in this application.

As previously disclosed, the parent of the subject application, U.S. Patent 6,716,830, is involved in a litigation styled *Bayer Healthcare AG, Alcon, Inc., and Alcon Research, Ltd. v. Teva Pharmaceuticals, USA, Inc.* (District of Delaware, C.A. No. 06-234). The trial in that litigation was recently completed. Applicants are submitting this Supplemental Information Disclosure Statement so as to inform the Examiner regarding the contentions made by the

Defendant with respect to the validity of the claims in the parent '830 patent. The submission of such information via this Supplemental Information Disclosure Statement should not be interpreted as an admission by Applicants as to the actual availability of the documents and/or other information cited herein as prior art to the invention claimed in the present application. Applicants recognize that this Supplemental Information Disclosure Statement includes a large number of documents. Applicants have therefore directed the attention of the Examiner to documents that provide relatively concise explanations of the Defendant's contentions relative to validity. See, in particular, the documents identified in the next three paragraphs.

The Defendant's expert report of Dr. Loyd Allen, which was previously submitted in an Information Disclosure Statement (IDS) filed September 6, 2007, outlines the Defendant's initial contentions of invalidity. Non-patent literature (NPL) Document Nos. 14-25 and U.S. Patent 5,149,693 on the first attached form PTO/SB/08a are exhibits to the Allen expert report. Copies of NPL Documents 14-25 are appended to previously-submitted Allen expert report and therefore are not being resubmitted at this time.

Also submitted are the Plaintiffs' expert reports of Alfonso (NPL Doc. 5), Mitra (NPL Doc. 6), and Zhanel (NPL Doc. 7).

In addition to the Allen expert report, Defendant's contentions regarding validity are discussed in the Plaintiffs' Responsive Interrogatory Concerning Defendants' Supplemental § 112, ¶ 1 Defenses (NPL Doc. 1), and the Defendant's Supplemental Responses to Plaintiffs' Interrogatories (NPL Doc. 2). The Examiner's attention is directed to the Defendant's Interrogatory Response No. 9 and the Schmitz (NPL Doc. 26) and Dalhoff (NPL Doc. 27) publications discussed therein. The Defendant's contentions are also discussed in the Defendant's pre-trial statements regarding issues of fact and law (third attached form PTO/SB/08a, NPL Docs. 31 and 32, respectively), and intended proofs (NPL Doc. 33).

Also submitted is a transcript from the trial, which spanned five days beginning February 28, 2008 (vol. B) and continuing March 3-6, 2008 (vols. C-F, respectively). The following table identifies the witnesses and indicates where their testimony can be found.

Witness	Testimony	Volume	Pages
Taylor (expert witness for Plaintiffs on infringement)	Direct	B	45 - 97
	Cross	B	98 - 146
	Re-Direct	B	147 - 154
Allen (expert witness for Defendant on invalidity)	Direct	B	155 - 215
	Direct	C	220 - 234
	Cross	C	234 - 366
	Re-Direct	C	366 - 370
Alfonso (expert witness for Plaintiffs on validity)	Direct	C	371 - 439
	Cross	C	440 - 481
	Cross	D	484 - 544
	Re-Direct	D	545 - 564
Stroman (named inventor)	Direct	D	564 - 621
	Cross	D	621 - 674
	Re-Direct	D	674 - 676
Alford (witness for Plaintiffs)	Direct	D	677 - 685
	Cross	D	686 - 690
Mitra (expert witness for Plaintiffs on validity)	Direct	D	691 - 715
	Direct	E	718 - 743
	Cross	E	744 - 807
	Re-Direct	E	807 - 825
Zhanel (expert witness for Plaintiffs on validity)	Direct	E	826 - 964
	Direct	F	967 - 984
	Cross	F	984 - 1115
	Re-Direct	F	1115 - 1145
	Re-Cross	F	1147 - 1148

Deposition testimony of inventor David Stroman, Ph.D. is also submitted herewith (NPL Doc. 28). Dr. Stroman is the only inventor named in the present application that was deposed during the district court litigation and is also the only inventor that provided testimony at trial. Applicants are submitting the transcript of Dr. Stroman's deposition so as to provide a complete record of the inventors' statements during the course of the district court litigation.

The Plaintiffs' Trial Exhibits that were admitted into evidence at trial are listed in the first attached form PTO/SB/08a as NPL Docs. 30-50 and in the second attached form PTO/SB/08a as NPL Docs. 1-50. The Defendant's Trial Exhibits that were admitted into evidence at trial are listed in the third attached form PTO/SB/08a as NPL Docs. 1-26. In addition, the following Defendant's Trial Exhibits are listed under U.S. patent and foreign patent references as follows: DTX0078 (US 5,149,693); DTX0227 (US 2007/0049552); DTX0230 (WO 00/1365); DTX0232 (US 2006/0276777); DTX0233 (US 2006/0183698); and DTX0234 (US 2006/0074053).

Applicants direct the Examiner's attention to the fact that as a part of the organization of the trial exhibits, prior to the trial, Plaintiffs and Defendant agreed to eliminate duplicate documents from the exhibit lists, such that the same document would not be identified via both a Plaintiffs' trial exhibit number and a Defendant's trial exhibit number. As a result, during the course of the trial, the Defendant sometimes cited, offered into evidence, and relied on Plaintiffs' trial exhibits and vice versa.

For the Examiner's convenience, a list of Defendant's trial exhibits (third attached form PTO/SB/08a, NPL Doc. 27) and a list of Defendant's trial exhibits that were admitted into evidence at trial (NPL Doc. 28) are attached. A list of Plaintiffs' trial exhibits is attached (NPL Doc. 29), as well as a list of Plaintiffs' trial exhibits that were admitted into evidence at trial (NPL Doc. 30).

Finally, a copy of Defendant's Supplemental Notice Pursuant to 35 U.S.C. § 282 is also submitted (NPL Doc. 29). The Notice contains numerous documents that are not relied on in the Allen expert report and which were not admitted as trial exhibits. It is believed that such documents are at most cumulative to those discussed in the Allen expert report, admitted at trial and/or submitted by Applicants in this application, and therefore copies are not submitted herewith.

The Examiner is invited to telephone the undersigned at the number listed below if doing so would be helpful to resolve any outstanding issues.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Date: May 8, 2008

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